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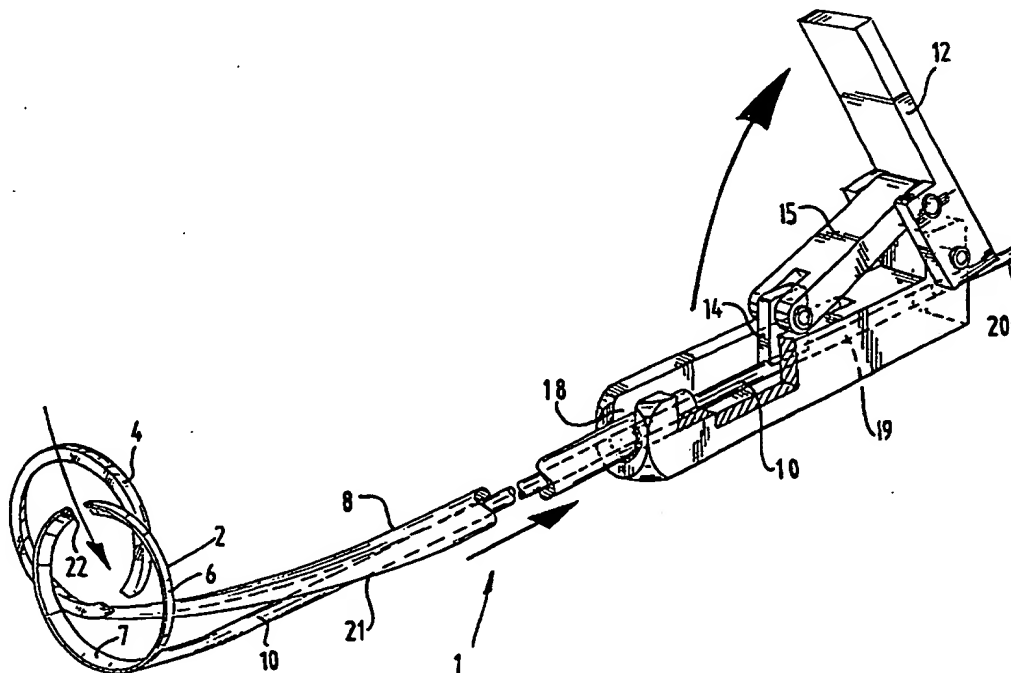
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## Published

With international search report.

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(54) Title: AN INSTRUMENT FOR LOOSENING AND CUTTING THROUGH THE INTIMA OF A BLOOD VESSEL, AND A METHOD THEREFOR



## (57) Abstract

The invention relates to an instrument for treating a blood vessel, comprising: loosening means of such a form as to pass between the wall of the blood vessel and the intima or tunica, which lines the inside of a blood vessel wall, for loosening the intima or tunica from the inside of the blood vessel wall; cutting through means for cutting through and severing the loose intima at a predetermined distance within the blood vessel; and support means for supporting the loosening and cutting means.

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AN INSTRUMENT FOR LOOSENING AND CUTTING  
THROUGH THE INTIMA OF A BLOOD VESSEL, AND  
A METHOD THEREFOR

The present invention relates to the treatment and cleaning of blood vessels.

It is known that narrowing or blockages (thromboses) can occur in blood vessels, particularly in older people. This is often caused by the effects of silting leading to hardening or calcifying of the blood vessels and their walls. This has dangerous consequences for the health, because the quantity of blood now able to flow through the blood vessel is drastically reduced. In order for effective blood circulation to occur and to avoid possible limb amputation for example, any blockage or obstacle in the blood vessels must be removed.

A device for the treatment of blood vessels is already known from the French patent application FR-A-2 635 962, which describes a device for completely removing varicose veins.

A complicated operation is presently necessary if hardening of the blood vessels occurs. In the case of the artery between the groin and the knee, this is quite a severe operation. The patient is cut open at the groin and the knee, whereafter the artery is completely removed and replaced by an artificial artery. This can be especially hard on and dangerous for old people particularly, because of the duration of the operation. The operation is also expensive and incorporates a lengthy hospital recovery period for the patient. Additionally there is a danger of rejection of the artificial blood vessel by the body, which can lead to further post operation complications.

There is thus a need for a quicker, less expensive, patient friendly procedure, for the cleaning of blood vessels, which obviates the above cited problems.

According to an aspect of the invention, an instrument is provided for treating a blood vessel comprising: loosening means of such a form as to pass

between the wall of a blood vessel and the intima or tunica, which lines the inside of a blood vessel wall, for loosening the intima or tunica from the inside of the blood vessel wall; cutting through means for cutting through and severing  
5 the loose intima or tunica at a predetermined distance within the blood vessel, wherein the blood vessel wall is left substantially intact and in place; and support means for supporting the loosening and cutting means.

The intima is a sort of innertube or innerlayer  
10 which is to some extent secured to the inner side of a blood vessel wall. All blood vessel blockages are found within the intima and thus it is sufficient, in order to remove these possible blockages from the blood vessel, to cut through the intima and remove it from the blood vessel. On removing an  
15 intima, a new intima grows to replace the old one. According to the present invention an instrument is provided which via a small incision can be pushed into the blood vessel, whereby the intima is separated from the blood vessel wall. The instrument then cuts through the intima at a required  
20 distance, for example where the hardening ends, whereafter the blockage can be removed by pulling the instrument back out of the blood vessel or by any other suitable method.

A blood vessel is able to be cleaned in this manner so that the need for a time consuming, expensive  
25 operation which is harsh on the patient is removed. The requirement of an artificial replacement blood vessel is no longer present, because the old blood vessel is now in a state to again effectively fulfill its function. Therefore rejection of an artificial blood vessel by the body, and its  
30 ensuing problems, do not play a role here. The hospital recovery period is shortened due to the less exacting nature of this operation, whereby the costs decrease and more hospital beds become available.

The loosening means preferably comprise a ring  
35 part with blunt edge. The ring part preferably has a cross section in the form of a truncated cone, the nose of which projects in the direction of the incision. In this way the blunt edge separates the intima from the blood vessel wall

when the instrument is pushed between the intima and the blood vessel wall. The intima is thus peeled further away from the blood vessel wall and is subjected to a sort of bottle neck effect, caused by the cone form, between the two  
5 sides of the ring.

The cutting through means preferably comprise at least two parts of such a shape that they can be inserted between the intima and the blood vessel wall, at least one part of these encircling parts being associated with moving  
10 means for moving this part with respect to the other part so that a scissor effect is obtained. These parts are preferably ring shaped, at least one of the rings having a sharp edge for cutting through the intima, and are preferably mounted at an angle next to each other at one end  
15 of the support. The supporting of the rings at an angle facilitates pushing of these parts between the intima and the blood vessel wall and reduces the probability of damage to the blood vessel wall.

The length of the support may depend on the length  
20 of the blood vessel to be cleaned, and/or the extent of calcification in the blood vessel.

The moving means preferably comprise a part, that can take the form of a filament or a wire, that extends through the support, which is preferably moved with respect  
25 to the support, by operating means at the opposite end of the support to the cutting through means and loosening means. The operating means preferably comprise a lever associated with the support. In this way the intima can be separated from the blood vessel wall and cut through at the  
30 required distance by the instrument, which is operable from outside the body.

A grip part is preferably associated with one end of the support and a lever is associated with this grip part. In this way a secure hold on the instrument is insured  
35 for pulling the instrument back out of the blood vessel, after the intima has been cut through.

The present invention also provides a method for loosening the intima or tunica from a blood vessel wall and

for cutting through the intima at a certain distance, comprising: making an incision in the blood vessel, placing the instrument in the blood vessel between the blood vessel wall and the intima, moving the instrument through the blood vessel, whereby the intima is loosened from the blood vessel wall over a determined distance and cutting through and severing the intima at that distance.

The separation of the intima from the blood vessel wall and the cutting through and severing of the intima is consequently quick and able to be carried out in an elegant and simple manner. After cutting through of the intima, the intima plus blockage are removed.

Further advantages, characteristics and details of the present invention will become clear from the following description which refers to the accompanying drawings, which show:

fig. 1 a partly broken away perspective view of an embodiment of the invention;

fig. 2 a perspective view of the embodiment from fig. 1, showing operation thereof;

fig. 3 the embodiment from fig. 1 applied to an embodiment of the method according to the present invention;

fig. 4 is a detail of part of the embodiment from figure 1 in the action of cutting through an intima.

An embodiment of the instrument 1 according to the invention (fig. 1) comprises two rings 2, 4 supported at an angle which are insertable around the intima, the front ring 2 having a blunt edge 6 as well as a hollow pin 8, a filament 10, moveable in the hollow pin 8, which is connected via a hinge 15 of the lever 12 with a projection 14 of the filament 10, a grip part 16, which also acts as base for the lever 12, and a slot 18 in the grip part 16 wherein the projection 14 and the moveable part 10 extend. The hollow pin 8 is secured to the grip part 16, whilst the filament 10 moves in the slot 18. The slot 18 narrows to a narrower slot 19 (fig. 1) which extends completely through the grip part 16.

In fig. 2, the lever 12 is in the raised position. On raising the lever 12, the filament 10 in the hollow pin 8, is displaced to the grip part 16, via the projection 14, so that a part 20 of the moveable part 10 moves through the channel 19 and projects out from the rearside of the grip part 16. On carrying out this action the front ring 2, which is supported by the moveable part 10, moves downwards with respect to the second ring 4, so that a scissor movement is obtained between the two rings 2, 4. The filament 10 extends out of the under side of the hollow pin 8 through an opening 21, whilst on the upper side the hollow pin 8 extends to the rings 2, 4.

The blunt edge 6 of the front ring 2 extends inwardly to a sharp inner edge 22 of the front ring 6 (figures 1 and 2).

An instrument 1 according to the invention is inserted into the artery 23, see figure 3, via a small incision 24 of about 8-10 cm in the groin, between the groin and the knee, in such a way that the rings 2, 4 extend in the direction of the knee whilst the lever 12 and the grip part 16 are located outside of the body, near to the incision 24 of the artery 23.

The front ring 2 is moved downwards with respect to the rear ring 4, by the scissor movement of the two rings 2, 4 (fig. 4), causing the intima 26, which is already separated from the blood vessel wall 28 to be pinched between the two rings 2, 4. It is clear that further downwards movement of the front ring 2 will result in the cutting through and severing of the intima 26 which is held between the sharp edge 22 of the front ring 2, supported by the hollow pin 8, and the rear ring 4, supported by the moveable part of filament 10.

The rings 2, 4 are preferably sharpened for about 40 %, or 144° of their contours, front ring 2 sharpened along its upper inner side and rear ring 4 sharpened along its lower inner side, in order to achieve a highly efficient shear, scissor-like cutting movement when front ring 2 is moved relative to rear ring 4. This scissor-like cutting

effect is particularly efficient in cutting through hardened, calcified material as relatively little mechanical force is needed in operation of the instrument, to effect a neat cut.

5           The rings 2, 4 are flattened where they meet, as shown in figure 2, in order to fit together as a single ring so that no obstructions project which could damage the outer layer of the blood vessel during insertion, operation and/or removal of the instrument.

10           From clinical tests it has been determined that an effective cutting through and severing is achieved when the rings are mounted at an angle of 45° relative to the filament and hollow pin. However it will be obvious that the rings could be mounted in any direction and in any relative  
15 position in order to achieve efficient cutting.

          At this angle of 45° it was found that the following ring diameters, with respect to the inner diameter of the blood vessel, yielded efficient separation of the intima from the blood vessel wall and cutting through and  
20 severing of the intima and any hardened, calcified material therein.

<u>Inner diameter blood vessel</u>	<u>diameter rings</u>
25           4 mm	6,5 mm
5 mm	7,5 mm
6 mm	8,5 mm

30

          On inserting the instrument into an already opened blood vessel (figures 3, 4) the front ring 2 and the rear ring 4 encircle the intima 26. The instrument is then pushed through the blood vessel. The blunt edge 6 of the front ring  
35 2 separating the intima from the blood vessel wall 28, whereby the intima 26 is forced further inwards away from the blood vessel wall by a funnel effect brought about by the front ring 2. After the two rings 2, 4 have been moved



to a required distance in the blood vessel, for instance to a point where there is no more blockage of the blood vessel, the movement is stopped and the lever 12 is raised which brings about the earlier stated scissor movement for the  
5 cutting through and severing of the intima.

In order to further improve cutting and severing, at least one of the rings, preferably the front ring 2, may be vibrated during the scissor movement.

The intima and the blockage therein can be removed  
10 either by removing the instrument from the blood vessel or by any other way.

It will be noted that the present invention is not limited to the embodiment as herein drawn and described, for instance in a further (not shown) embodiment of the present  
15 invention the filament and hollow pin may be reversed so that the filament extends out of an opening on the upperside of the hollow pin, the position of the filament's and hollow pin's respective rings being reversed, whereupon cutting is achieved by pushing the filament instead of pulling the  
20 filament, and in yet another (not shown) embodiment of the present invention, the hollow pin may be pushed to achieve a cutting movement, instead of pulling the filament.

A further advantage of the present invention is that blocked blood vessels, specifically the artery between  
25 the groin and the knee, can be unblocked to allow the insertion, via this artery, of a prosthetic into the aorta to treat patients who, along with blocked blood vessels, also have aneurisms for instance. For these patients the chest now no longer has to be opened in order to treat the  
30 aneurism, as the now, unblocked artery between the knee and the groin yields a prosthetic access to the aorta.

A large number of modifications and variations are conceivable within the range of the following claims.

## CLAIMS

1. An instrument for treating a blood vessel, comprising:

- loosening means of such a form as to pass between the wall of the blood vessel and the intima or

5 tunica, which lines the inside of a blood vessel wall, for loosening the intima or tunica from the inside of the blood vessel wall;

- cutting through means for cutting through and severing the loose intima at a predetermined distance within  
10 the blood vessel; and

- support means for supporting the loosening and cutting means.

2. An instrument according to claim 1, wherein the loosening means comprise at least one part of such a shape  
15 as to pass between the blood vessel and the intima during treatment, said part encircling the intima.

3. An instrument according to claims 1 or 2, wherein the cutting through means comprise at least two parts of such a shape, as to pass between the blood vessel  
20 and the intima, and whereby at least one first part is associated with moving means for moving the first part with respect to the other part.

4. An instrument according to claims 1, 2 or 3, wherein the support means comprise a cavity member, such as  
25 a hollow pin, of such a shape as to be insertible into the blood vessel.

5. An instrument according to any of the preceeding claims wherein the moving means comprise a part, such as a filament, moveable with respects to the pin, which  
30 is associated at one end with at least one part of the cutting through means, and which, by operating means at the other end of the support from the cutting means, is operable.

6. An instrument according to claim 5, wherein the  
35 operating means and the support means are integrated in such

a way, that the moveable part is moved with respect to the support during operation of the operating means.

7. An instrument according to any previous claim, wherein the cutting through means and the loosening means  
5 are formed by at least two rings.

8. An instrument according to claim 7, wherein at least one ring has a cross section in the form of a truncated cone, the nose of which projects in the direction of the operating means.

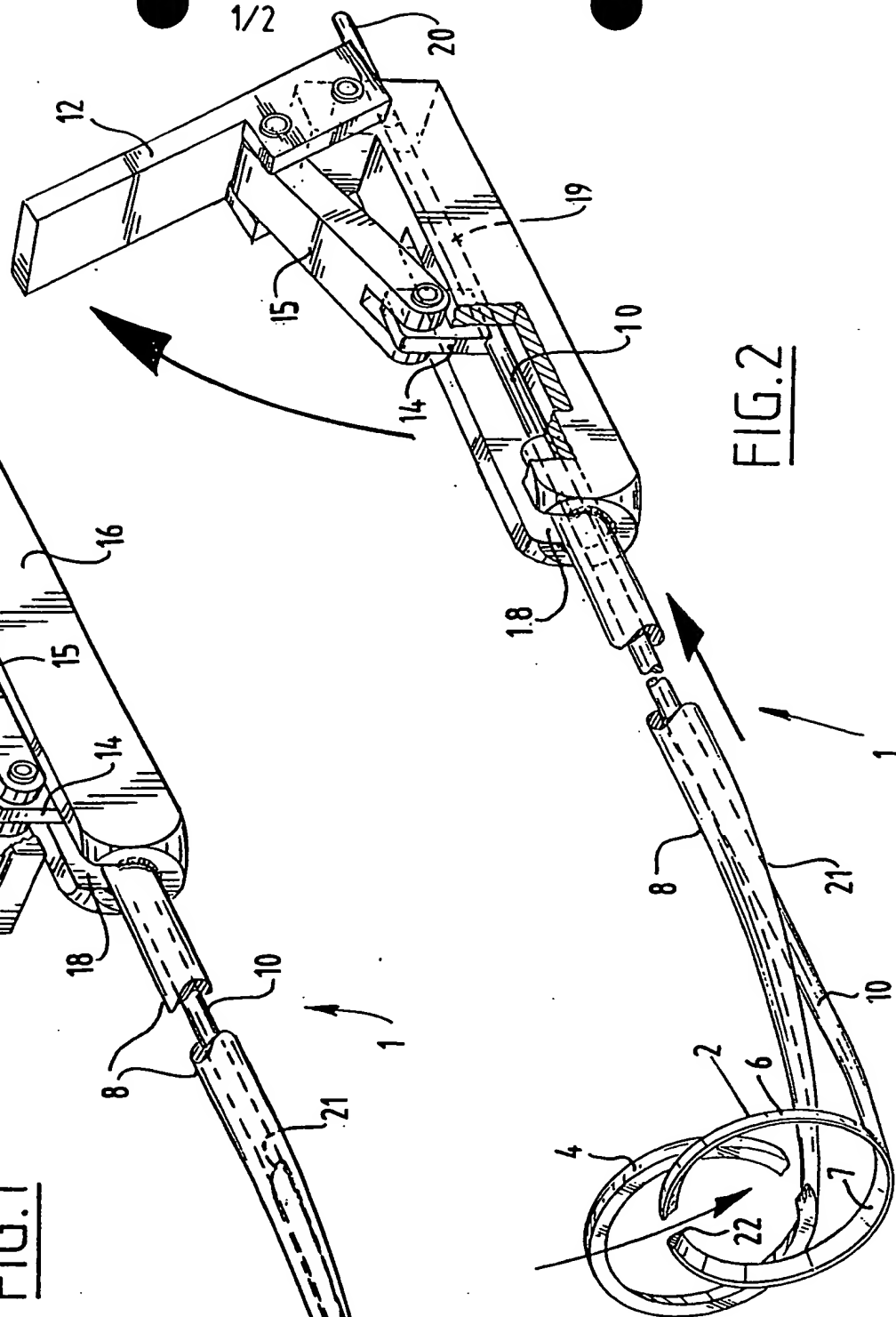
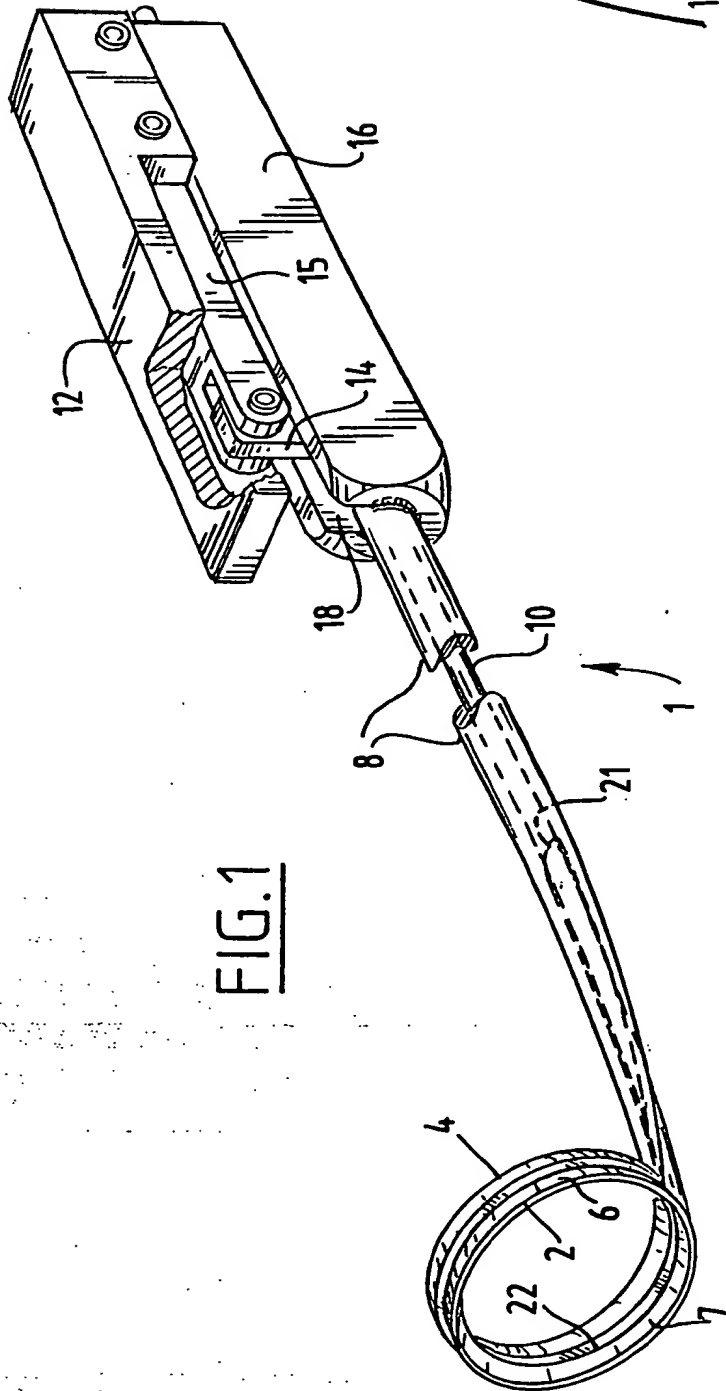
10 9. An instrument according to claim 8, wherein an edge of at least one ring is blunt.

10. An instrument according to claim 9, wherein an edge of at least one ring is sharp.

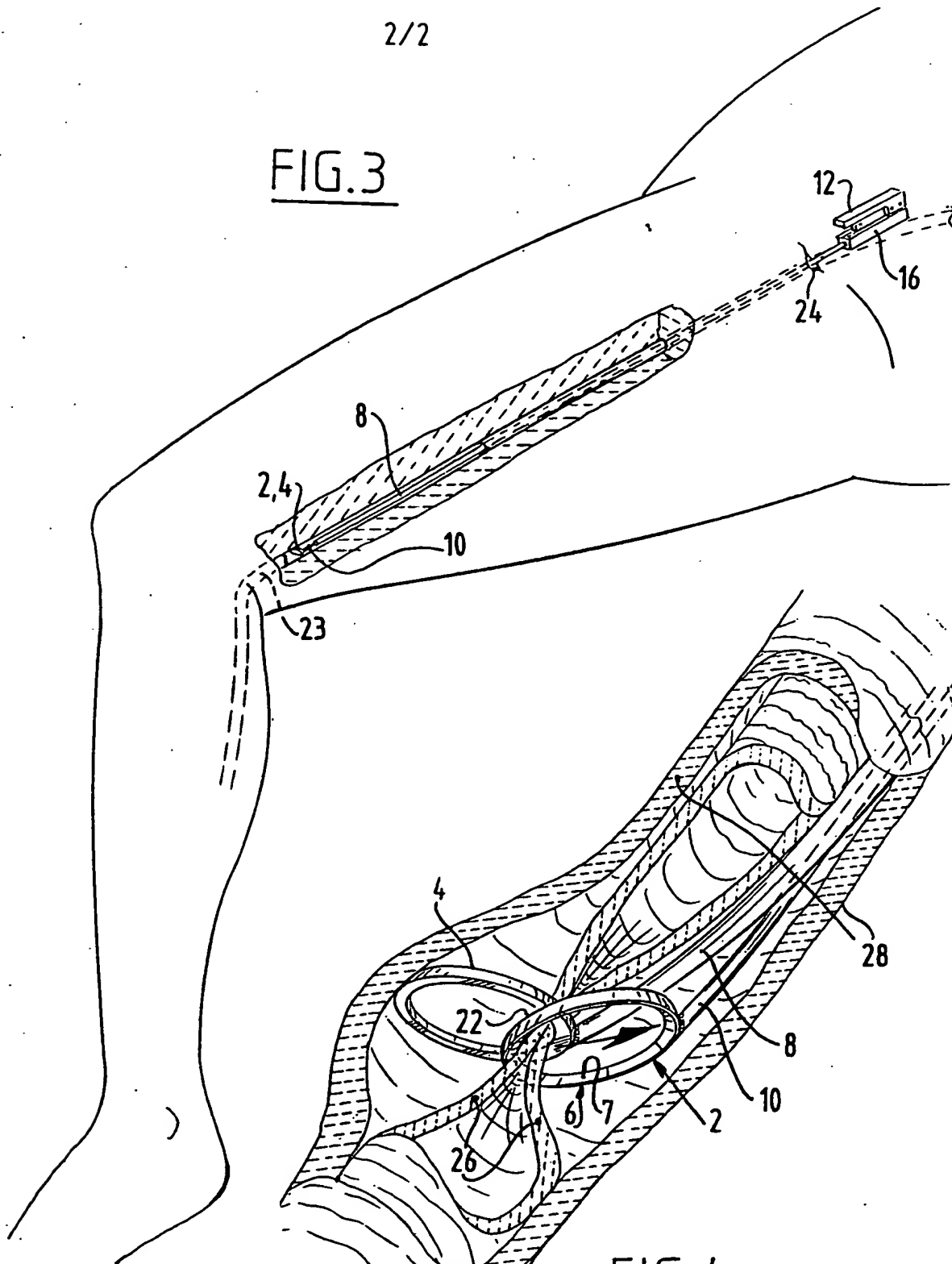
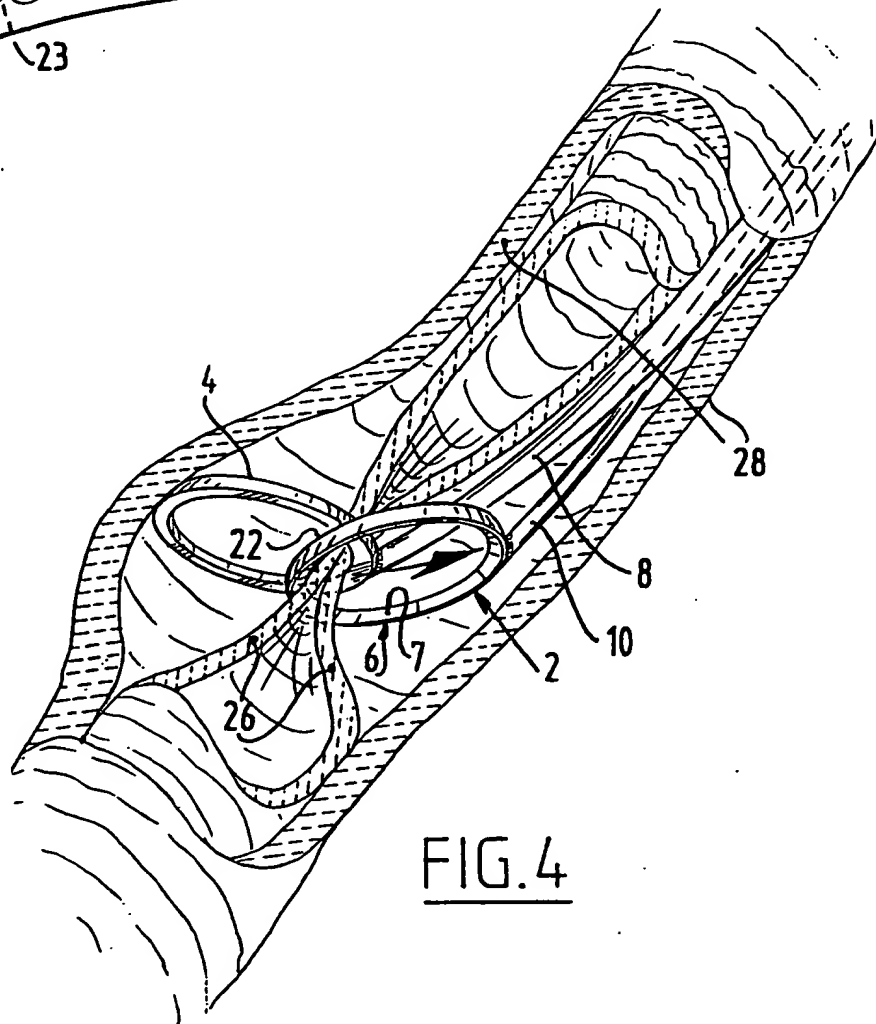
11. An instrument according to any of the  
15 preceeding claims, wherein at least one grip part is associated with one end of the support.

12. A method for loosening the intima or the tunica from a blood vessel and for cutting through and severing the intima at a determined distance, comprising:  
20 making an incision in the blood vessel, placing the instrument in the blood vessel between the blood vessel wall and the intima, moving the instrument through the blood vessel, whereby the intima is loosened from the blood vessel wall over a determined distance and cutting through and  
25 severing the intima at that distance.

13. A method according to claim 12, wherein an instrument is used according to one or more of the claims 1 to 11 and or according to one or more aspects of the description and/or figures.



2/2

FIG.3FIG.4

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/22 A61B17/32 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR,A,2 635 962 (TRAUCHESSEC) 9 March 1990 cited in the application see page 1, line 29 - line 38; figures 1,2	1-7,11
Y	US,A,2 944 552 (CANNON) 12 July 1960 see claim 1; figures 1,5	1-7,11

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
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\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

21 February 1995

Date of mailing of the international search report

03.03.95

Name and mailing address of the ISA

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**Box I. Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 12, 13  
because they relate to subject matter not required to be searched by this Authority, namely:  
Method for treatment of the human or animal body by surgery: Rule 39.1 (iv).
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

information on patent family members

International application No.

PT/NL 94/00254

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2635962	09-03-90	NONE	
US-A-2944552	12-07-60	NONE	